510(k) Summary of Safety and Effectiveness

MAY 11 2006

Submitted By:

Life Spine
2400 Hassel Road Suite 370
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510(k) Contact:

Erin Malloy
Life Spine
2400 Hassel Road Suite 370
Hoffman Estates, IL 60195

Date Prepared: January 30, 2006

Trade Name: Life Spine Cement Restrictor

Common Name: Cement Restrictor

Classification: Prosthesis, Surgical Mesh
CFR 878.3300
Class II

Device Product Code: JDK

Predicate Device: SIGNUS Medical RABEA™ Cement Restrictor

Device Description:

The device is a straight or tapered hollow box with a fenestrated surface on many sides. The geometry is designed to contain bone cement. The exterior surface of the device has teeth to prevent the device from migrating from the desired location. The device is manufactured from PEEK-OPTIMA®. The device is made in a variety of sizes. The responsible surgeon will determine the correct size of the device in accordance with the anatomical size of the individual patient.

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED

Intended Use of the Device:

The Life Spine Cement Restrictor is intended for use in orthopedic surgeries involving the femoral canal, tibia, or the humerus..

This device is NOT intended for use in any spinal indications or acetabular cup surgeries. The safety and effectiveness of this device for implantation in the spine has not been established.

Material:

The Life Spine Cement Restrictor is manufactured from PEEK-OPTIMA® according to ASTM F 2026-02.

Performance Data:

This is designated as a non-load bearing Class II device under CFR 21 878.3300 and no mechanical tests are required.

This device is manufactured from PEEK-OPTIMA®. The previously cleared SIGNUS Medical RABEA™ Cement Restrictor was also manufactured from PEEK-OPTIMA®, which complies with ASTM F2026. The biocompatibility of this material for implantable contact over 30 days has been certified to ISO 10993 by the manufacturer of PEEK-OPTIMA®, Invibio. The Food and Drug Administration retains a Device Master File containing the biocompatibility information.

Substantial Equivalence:

The Life Spine Cement Restrictor was shown to be substantially equivalent to previously cleared device, the SIGNUS Medical RABEA™ Cement Restrictor, in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2006

Life Spine
c/o Erin Malloy
2400 Hassell Road - Suite 370
Hoffman Estates, Illinois 60195

Re: K060247
Life Spine Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDK
Dated: March 17, 2006
Received: March 20, 2006

Dear Ms. Malloy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm.

Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K060247

Device Name: Life Spine Cement Restrictor

The Life Spine Cement Restrictor is indicated for use as a cement restrictor in the femur, tibia, or humerus.

This device is not intended for spinal indications or acetabular cup surgeries. The safety and effectiveness of this device when implanted in the spine have not been established.

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED

Prescription Use __x__ (Part 21 CFR 801 Subpart D)	And/Or	Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Mark N Milhenza

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
(510(k) Number K060247